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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,953	04/15/2004	Kenneth T. Heruth	1023-363US01	8229
28863 7590 04/03/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER GEDEON, BRIAN T	
			ART UNIT	PAPER NUMBER
			3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/825,953	HERUTH ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 14-16, 22-35, 37, 38, 44-47 and 50-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47 and 50-75 is/are allowed.
- 6) ☒ Claim(s) 1-3, 22-26, 44, 46, 76 and 77 is/are rejected.
- 7) ☒ Claim(s) 4-12, 14-16, 27-35, 37, 38, and 45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/2/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 23-26, 44, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Hatlestad et al. (US PG-Pub 2005/0042589 A1).

In regard to claims 1, 24, and 76, Hatlestad et al. describes a sleep quality detection system that detects physiological and non-physiological conditions associated with sleep quality, with means for determine metrics based on the detected conditions associated with sleep and things that disrupt sleep [0022]. The means for detecting and calculating metrics is a processor [0022]. The sleep quality system is coupled to a therapy unit 324 [0071]. Further, Hatlestad et al. compare the sleep quality metric value to a threshold value [0079] in order to determine a patient's sleep state, whereby Hatlestad et al. teaches that the sleep state may be used for adjusting therapy [0054], which the Examiner interprets anticipating the step for adjusting the therapy based on the threshold comparison.

In regard to claims 2, 3, 25 and 26, the sleep detection system of Hatlestad et al. has many sensors for monitoring physiological parameters such as patient activity,

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patient location, posture, heart rate, QT interval, eye movement, respiration rate, transthoracic impedance, tidal volume, minute ventilation, brain activity, muscle tone, body temperature, time of day, and blood oxygen levels [0081] and [0132]; see Table 1.

In regard to claims 23 and 44, the medical device of Hatlestad et al. utilizes implantable components [0055]. Figure 3 of Hatlestad et al. shows a cardiac therapy module contained within the system.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 22, 46, and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatlestad et al. (US PG-Pub 2005/0042589 A1) in view of Civelli et al. (US Patent no. 6,884,596).

In regard to claims 22, 46, and 77, Hatlestad et al. substantially describe the invention as claimed except treatment of chronic pain. Civelli et al. provide a teaching that chronic pain is known to reduce sleep quality, col 7 lines 37-41. Further Hatlestad et al. teach that untreated, sleep disturbances may have a number of adverse health and quality of life consequences [0013], and serves the objective of determining events that disrupt sleep [0025] in order to provide adjustments to therapy in order to improve sleep quality [0054]. Since chronic pain is known to reduce sleep quality it would have

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been obvious to one of ordinary skill in the art at the time the invention was made to modify Hatlestad et al. in view of Civelli et al. in order to improve sleep quality by adjusting or applying therapy to appropriately treat any event that disrupts sleep quality.

***Terminal Disclaimer***

3. The Terminal Disclaimer filed 10 October 2006 has been approved. The double patenting rejection has been withdrawn.

***Allowable Subject Matter***

4. Claims 47 and 50-75 are allowed.

5. The following is an examiner's statement of reasons for allowance: Independent claims 47, 50, 54, 58, 63, 67, and 71 contain subject matter that was previously indicated allowable.

6. Claims 4-12, 14-16, 27-35, 37, 38, and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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